Krystexxa access in the UAE: the MOHAP and EDE named-patient pathway

How UAE patients with chronic refractory gout legally obtain Krystexxa (pegloticase) from US-source supply when the medicine is not commercially registered locally.

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Quick orientation

Krystexxa (pegloticase) is a pegylated recombinant uricase enzyme approved by the US FDA in 2010 for chronic refractory gout in adults whose oral urate-lowering therapy (allopurinol, febuxostat) has failed or is contraindicated. The label was expanded in 2022 to include co-administration with methotrexate, which substantially improves response durability and reduces infusion-reaction frequency. Krystexxa's international footprint is exceptionally narrow: the EMA authorisation was withdrawn at the manufacturer's request in 2016, and Krystexxa is not commercially registered in the EU, UK, Japan, Canada, or in most Middle East and South Asia markets. For UAE patients with disabling tophaceous gout that has failed oral therapy, the named-patient pathway administered by the Ministry of Health and Prevention (MOHAP) and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal is the primary legal route. Reserve Meds handles the US-side specialty sourcing, the cold-chain logistics, and the documentation kit your rheumatologist needs.

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Why UAE patients need Krystexxa via the named-patient pathway

The UAE federal regulatory environment is one of the most developed in the Gulf, with MOHAP holding the national drug register and the EDE assuming 44 core services from December 2025. For Krystexxa, the operative access gap is straightforward: the drug is not commercially registered in the UAE. There is no clinically equivalent uricase product on the local register, and the patient population that qualifies (chronic refractory gout, already failed allopurinol at maximum tolerated dose and failed or cannot tolerate febuxostat) typically continues to deteriorate on oral regimens that are no longer adequate.

Pegloticase sits in an unusually clean compassionate-use profile for international cases. The clinical population is small but the unmet need is intense. Tophi continue to grow, joints continue to erode, and quality of life deteriorates despite years of oral therapy. Pegloticase is uniquely effective at rapidly lowering serum uric acid to levels that mobilize and dissolve monosodium urate deposits. The narrow biologic mechanism, the cold-chain shipping requirement, the IV infusion administration, and the absence of commercial registration outside the United States place this case profile clearly inside the named-patient lane rather than any commercial import channel. UAE patients with visible tophi causing disability or recurrent severe gout flares despite optimised oral therapy are the natural fit for the pathway.

The MOHAP and EDE named-patient pathway for Krystexxa

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered locally is the unregistered-medicine import permit. Historically administered by MOHAP and from 29 December 2025 administered through the EDE portal at ede.gov.ae under Federal Decree-Law No. 38 of 2024, the framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA in this case) and a clinically equivalent locally registered alternative is not suitable. Chronic refractory gout with disabling tophi fits the framework's serious-illness scope.

A complete Krystexxa application typically includes:

- A clinical justification letter from the treating rheumatologist (chronic gout with refractory status, documentation of allopurinol at maximum tolerated dose with failure, documentation of febuxostat failure or contraindication, presence of tophi or recurrent severe flares, and the rationale for pegloticase as the next step)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, matched to the dispensing facility's emirate)
- A patient identifier (anonymised reference is preferred where the EDE submission allows), and critically, documentation of G6PD screening status (see clinical-letter section below)
- Full product details: Krystexxa (pegloticase), Amgen Inc. (acquired from Horizon Therapeutics in October 2023), 8 mg single-dose vial in 1 mL sterile solution, with the quantity reflecting the planned every-2-week IV cycle (often 6 to 12 months on monotherapy, or longer on the methotrexate co-administration regimen)
- The destination dispensing facility: a rheumatology infusion suite or hospital infusion center capable of compounding the IV bag under aseptic technique, with anaphylaxis-management capability (IV access, resuscitation drugs, trained staff)
- A chain-of-custody plan describing how Krystexxa will move from the US specialty distributor through the importer to the dispensing pharmacy under continuous 2 to 8 degree Celsius cold chain, light-protective packaging, and continuous temperature monitoring

For Krystexxa, the clinical justification letter carries a specific weight that is unique among the drugs Reserve Meds coordinates: G6PD deficiency status. Krystexxa is contraindicated in patients with G6PD deficiency because of the risk of life-threatening hemolytic reactions and methemoglobinemia. The FDA label specifically flags patients of African, Mediterranean (including Southern European and Middle Eastern), and Southern Asian ancestry as at increased risk. For the UAE patient population, where Emirati and many expatriate ancestries fall within these risk groups, G6PD screening before initiation is mandatory and the documentation must be in the patient file. Approval timelines for routine UAE cases are typically 5 to 15 business days. First-time imports of a complex biologic with G6PD-screening prerequisite may extend to 4 to 6 weeks.

Where Krystexxa gets dispensed in the UAE

Krystexxa is an IV biologic administered over no less than 120 minutes every two weeks under supervised conditions capable of managing anaphylaxis. The dispensing facility must have rheumatology infusion capacity, an aseptic compounding pharmacy capable of preparing the diluted IV bag within the 4-hour post-dilution window, and emergency-management readiness for anaphylaxis. The UAE institutions that handle named-patient imports as established workflow and carry rheumatology infusion capability include Cleveland Clinic Abu Dhabi (the M42 group's 364-bed multispecialty hospital with rheumatology and pharmacy services accredited by the American Society of Health-System Pharmacists), Sheikh Khalifa Medical City in Abu Dhabi (the SEHA network's 586-bed JCI-accredited tertiary center managed by the Cleveland Clinic), American Hospital Dubai (Mayo Clinic Care Network member with rheumatology services), King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City.

The larger NMC Healthcare sites and Tawam Hospital in Al Ain can also support Krystexxa cases through in-house infusion-pharmacy infrastructure. For patients in the Northern Emirates without a local rheumatology infusion center capable of anaphylaxis management, the practical pattern is to route to a Dubai or Abu Dhabi center where the treating rheumatologist holds privileges or where the case is co-managed with a UAE-licensed colleague.

Real cost picture for Krystexxa in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. Public WAC data points indicate Krystexxa's per-vial price has risen substantially since launch. Recent regulatory and pricing references cite an annual WAC

of approximately USD 650,000 for the standard every-2-week regimen (approximately AED 2.39 million per year), which implies a current per-vial WAC in the range of USD 25,000 per vial. Exact current per-vial WAC figures sit behind paywalled pricing databases as of this review, and the per-vial estimate should be confirmed at the time of any patient-specific quote. International payers do not list Krystexxa on standard formularies in EU, UK, or GCC markets.

International logistics for a refrigerated liquid biologic with continuous temperature monitoring typically runs USD 800 to 1,500 (approximately AED 2,900 to 5,500) per shipment, depending on the destination emirate and urgency window. UAE customs and EDE permit fees are nom